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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,417	07/01/2003	Denis Leclerc	1398-104US	9472
<div>50438 7590 09/11/2007</div> <div>JUNEAU PARTNERS P.O. BOX 2516 ALEXANDRIA, VA 22301</div>				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/609,417	Applicant(s) LECLERC ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-25 and 27-58 is/are pending in the application.
- 4a) Of the above claim(s) 31,40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25,27-30,32-39 and 42-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

The Amendment filed June 20, 2007 in response to the Office Action of April 2, 2007 is acknowledged and has been entered. Claims 20 and 27 are amended. New claims 55-58 are added. Claims 20-25, 27-30, 32-39, and 42-58 are under examination.

Information Disclosure Statement

The information disclosure statement filed June 20, 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited non-patent literature publication or that portion which caused it to be listed. The document by Richard Ikegami, 1995, has not been considered because the quality of the printed text is not legible.

The Information Disclosure Statement received June 20, 2007 with regard to the document by Tim Sit has been considered.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25, 27-30, 32-39, and 42-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1648

Claims are drawn to a method of potentiating an immune response against an antigen comprising B-cell antigenic and/or T-cell antigenic epitopes, the method comprising the step of administering to an animal an antigen and an effective amount of an adjuvant, wherein said adjuvant is a papaya mosaic virus (PapMV) or a virus-like particle comprising PapMV coat protein or modified PapMV coat protein wherein the antigen is not linked to PapMV, or is fused or covalently attached to a coat protein of PapMV coat protein at a location other than N-terminus.

The claims are rejected because the specification does not provide an adequate written description for the claimed method of potentiating an immune response comprising administering an antigen covalently attached to a modified PapMV coat protein. The specification defines the claimed modified PapMV as follows:

[0063] The first (viral) portion of the fusion protein may be any protein, polypeptide or parts thereof, derived from a viral source including any genetically modified versions thereof (such as deletions, insertions, amino acid replacements and the like). In certain embodiments, the first portion will be derived from a viral coat protein (or a genetically modified version thereof). Mention may be made of the coat protein of Papaya Mosaic virus as being suitable for this purpose. A fusion protein molecule can assemble with other fusion protein molecules or with wild-type coat protein into a immunogen-carrier virion.

Besides discussing general modifications as deletions, insertions, amino acid replacement and like the specification does not provide further guidance with regard to the modifications that are to be made within the PapMV coat protein in order for the PapMV particle to successfully assemble as a VLP and be useful in the method of potentiating an immune response.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

Art Unit: 1648

the claimed product, or any combination thereof. In the present case Applicant failed to identify the specific distinguishing characteristics of the claimed modified PapMV VLPs. The skilled artisan would expect that at least some modifications to the coat protein of the PapMV would result in failure of the PapMV to multimerize and assemble into a viral like particle.

Trembley et al. (FEBS Journal, 2006, Vol. 273, p. 14-25) teach that certain mutations within capsid protein of PapMV result in failure of PapMV to self assemble into a virus like particle. Applicant did not provide guidance with respect to which mutations, insertions or amino acid replacement within the capsid protein of PapMV would be permissible without risking the failure of the modified PapMV to assemble into a VLP. It is also noted that a modified PapMV that fails to assemble into a VLP, will also fail to induce immune responses as required by the present claims. Applicants' claims pertain to a function which is multimerization and formation of a PapMV viral like particle, however neither the claims or the specification provide an adequate written description for the structures of the modified PapMV capsid proteins that must perform the claimed function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the permissible mutations or

Art Unit: 1648

insertions that will allow the PapMV to assemble into a VLP, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Thus in view of the reasons set forth above the skilled artisan would not have recognized that Applicant was in possession of the claimed invention.

Claim Rejections - 35 USC § 102

Rejection of claims 20-24, 25, 27-30, 32-35, 38, 39, 42-54 under 35 U.S.C. 102(b) as being anticipated by Lee-Shanok (Construction and preliminary characterization of papaya mosaic virus as an expression vector for the presentation of foreign epitopes, Thesis for Degree of Master of Science, University of Toronto, 1999) **is withdrawn** in view of Applicant's amendment.

Lee-Shanok does not disclose a method of potentiating an immune response wherein the antigen is not linked to PapMV, or is fused or covalently attached to a coat protein of PapMV coat protein at a location other than N-terminus.

Claim Rejections - 35 USC § 103

Rejection of claims 36 and 37 under 35 U.S.C. 103(a) as being unpatentable over Lee-Shanok (Construction and preliminary characterization of papaya mosaic virus as an expression vector for the presentation of foreign epitopes, Thesis for Degree of Master of Science, University of Toronto, 1999) **is withdrawn** in view of Applicants' amendment.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on Monday – Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 8-27-2007
Primary Examiner, TC1600